REMARKS

Claim 1 has been amended to delete the "characterized by" phraseology. Claims 9-12 have been objected to for being in improper form as multiple dependent claims depending from another multiple dependent claim. In response, claims 9-12 have been amended so that they no longer depend from a multiple dependent claim. Therefore, withdrawal of this objection is respectfully requested. No new matter has been added.

Claims 1-8 have been rejected under 35 U.S.C. § 103(a) over U.S. Patent 6,737,044 (*Dickinson*). This rejection is respectfully traversed.

Claim 1 is directed to a dry powder inhalation composition comprising medicament particles and a mixture of lactose particles. The lactose particles have a volume mean diameter (VMD) of between about 70 and about 120 microns and a diameter of less than 250 microns. The claim also recites that the lactose particle mixture includes a fraction of smaller particles and a fraction of larger particles, in which up to 96% by weight of the lactose particles are less than 150 microns in diameter and up to 25% by weight of the lactose particles are less than 5 microns in diameter. The Office action also contains an acknowledgement that this feature is not taught by *Dickinson*.

The claimed invention is distinguishable from *Dickinson* in yet another respect. The composition of the present invention is a "dry powder" inhalation composition, whereas the compositions disclosed in *Dickinson* are aerosol compositions, in which particulates are liquefied or suspended in a propellant. Since the Patent Office did not address this distinction in the Office action, the Patent Office has not established a *prima facie* case of obviousness.

In any event, Applicant submits that the claimed invention would not have been obvious over the teachings of

Dickinson. As shown in Example 4 in the present specification, the recited lactose particle distribution (*i.e.*, "up to 96% by weight of lactose particles having a particles size less than 150 μm or up to 25% by weight of lactose particles having a particles size less than 5 μm"), was found to provide a more consistent delivery of medicament than conventional dry powder inhalation compositions. *Dickinson* discloses its composition for use only in an aerosol delivery system. In an aerosol delivery system, the medicament and particulates are suspended in a propellant. As disclosed in column 7, lines 5-19, *Dickinson* emphasizes that the amount and size of each of its particulates are at least in part dependant upon their solubility in the propellant. There is no disclosure or suggestion in *Dickinson* that would have motivated one of ordinary skill in the art to reformulate the aerosols into a dry powder, and to change the size distribution of the lactose particles without regard as to solubility in a propellant, and with a reasonable expectation that the resultant formulation would provide an advantage compared to conventional dry power formulations.

In view of the foregoing, reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

With regards to claims 9-12, which depend from claim 1, they are also believed to be patentable over the cited prior art for all the foregoing reasons.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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